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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,242	10/15/2001	Olga Bandman	PF-0451-2 DIV	4454

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EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,242	BANDMAN ET AL.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,9,10,12-16,28,29 and 58-63* is/are pending in the application.

4a) Of the above claim(s) *9,10,14-16,28,29 and 58-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/8/04; 10/15/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 3-7 and 12-13 in paper filed 1/8/04 is acknowledged. The traversal is on the ground(s) that rejoinder applies to the remaining. Rejoinder will be considered upon allowance of the product claim. The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claims 58-63 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are directed to arrays and use of arrays and these are classified in 435/287 and 288.1, for example. No arrays were claimed in the original set of claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 3-7, 9-10, 12-16, 28-29 and 58-63 are pending.

Claims 9-10, 14-16, 28-29 and 58-63 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 3-7 and 12-13 are currently under consideration.

Information Disclosure Statement

The IDS filed 1/8/04 and 10/15/01 have been considered and an initialed copy of the PTO-1449's are enclosed.

Priority

Applicant is requested to update the continuing data found at the first line of the specification. Applicant should include patent numbers, if applicable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-7 and 12-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5932475. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of claims is that the scope of the instant set of claims includes fragments and variants (which makes the scope broader).

Claim Rejections - 35 USC § 112

Claims 3, 6-7 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for polynucleotides of sequence of SEQ ID NO: 2, or for nucleic acids encoding SEQ ID NO. 1, does not reasonably provide enablement for all "naturally occurring" or "at least 90%" which reads on "*variants*" or *natural allelic variants*, either due to degeneracy of the genetic code. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the polynucleotides of sequence of the claimed sequences the specification fails to provide guidance as to how to determine the nucleic acid residues which will encode for functional "variants" of the encoded product. There is no disclosure in the specification that defines "variants" nor sufficient guidance as to how one of skill in the art would arrive at the claimed invention. Despite knowledge in the art for producing

polynucleotide variants, the specification fails to provide adequate guidance regarding what deletions from or alterations in the disclosed sequences result in polynucleotide variants due to the degeneracy of the genetic code, that encode a similar SEQ ID No. 1-like polypeptide. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of polynucleotide fragments and variants where the expectation of retaining similar encoding function is unpredictable based on the instant disclosure. Detailed information regarding the structural and functional requirements of the SEQ ID NO. 1 is lacking. Therefore, predicting which nucleic acid variants that would encode amino acids that would maintain function is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the location, size, and sequence of deletions and alterations which preserve the encoding activity, in order to make and use polynucleotides, probes, vectors, host cells and recombinant methods in a manner reasonably commensurate with the scope of the claims.

Claims 3 and 6-7 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art

can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated DNA molecules
a) encoding a polypeptide comprising SEQ ID NO. 1
b) encoding a polypeptide encoded by a sequence that is at least 90% identical to SEQ ID NO. 1.
c) comprising SEQ ID No. 2 or
d) a sequence that is at least 90% identical to SEQ ID NO. 2.

The claims are further drawn to host cells transfected with the above sequences.

The specification discloses an isolated cDNA sequence, SEQ ID NO: 2, which encodes a predictive polypeptide sequence, SEQ ID NO. 1.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be acheived by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural freatures common to members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Furthermore, the specification as filed does not provide adequate written description support for a polypeptide having at least 90% sequence identity to SEQ ID NO:1. Polypeptides having diverse functions are encompassed by the phrase 90% identity. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase 90% sequence identity" and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotech., 18(1):34-39,

2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claims 3, 6-7 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for polynucleotides encoding the amino acid sequence of SEQ ID NO:1, or for polynucleotides encoding SEQ ID NO:2, does not reasonably provide enablement for all "*fragments*" of such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the nucleotides that encode SEQ ID NO:1 and SEQ ID NO:2, the specification fails to provide guidance as to how to determine the nucleic acid residues which will encode for functional fragment of the gene product. While the specification defines polypeptide "*fragments*" as ranging in size from five amino acid residues to one amino acid residue less than full length (see page 6+, in particular); and defines polynucleotide "*fragments*"

as those which are greater than 60, polynucleotides in length, there is no disclosure of actual polynucleotides encoding either fragments of SEQ ID NO:1 or fragments of polynucleotides encoding SEQ ID NO:2. Despite knowledge in the art for producing polynucleotide fragments, the specification fails to provide guidance regarding what deletions from or alterations in the disclosed sequences result in polynucleotide fragments that encode a functionally similar sequence. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of polynucleotide fragments where the expectation of retaining similar encoding function is unpredictable based on the instant disclosure. Detailed information regarding the structural and functional requirements of the SEQ ID NO. 1 is lacking. Therefore, predicting which amino acid fragments would maintain function is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the location, size, and sequence of deletions and alterations which preserve the encoding activity, in order to make and use polynucleotides, probes, vectors, host cells and recombinant methods in a manner reasonably commensurate with the scope of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh